

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

RICHARD BOHNER,
Plaintiff,
v.

**CIVIL ACTION
NO. 15-4088**

SYLVIA MATTHEWS BURWELL,
Secretary of Health and Human Services,
Defendant.

:
:
:
:
:
:
:

Jones, II J.

December 1, 2016

MEMORANDUM

Richard Bohner (“Plaintiff”), was one of four Synthes executives prosecuted as “responsible corporate officers” after Synthes promoted the off label use of surgical bone cement manufactured by its corporate subsidiary. Plaintiff and the other executives pled guilty to a single strict liability misdemeanor offense under the Federal Food Drug and Cosmetics Act (“FDCA”). For his involvement, Plaintiff was sentenced to an eight-month term of imprisonment and a \$100,000 fine. As a result of and soon after Plaintiff’s conviction, Sylvia Burwell (“Defendant”), Secretary of the Department of Health and Human Services (“HHS”), elected to exclude Plaintiff from federal health care program participation for a period of four years, pursuant to 42 U.S.C. § 1320a-7(b)(1).¹ Plaintiff unsuccessfully challenged the exclusion decision before an administrative law judge, and then again before the Departmental Appeals Board (“DAB”) of HHS, arguing that the crime for which he was convicted could not justify exclusion under § 1320a-7(b)(1). In Plaintiff’s view, Defendant erred when Plaintiff’s conduct, and not his offense of conviction, served as the basis of Defendant’s decision to exclude Plaintiff from program

¹ § 1320a-7(b)(1) of Title 42 is also referred to as § 1128 of the Social Security Act. In the interest of consistency and to avoid confusion, this Court uses the section numbering derived from the U.S. Code – 42 U.S.C. § 1320a-7(b)(1) (“§ 1320a-7(b)(1)”).

participation. Plaintiff advances that same argument before this Court today, and we are similarly unpersuaded.

Plaintiff initiated the present action appealing the decision of the DAB to uphold Plaintiff's exclusion from participation in federal health care programs under § 1320a-7(b)(1). The parties filed cross motions for summary judgment, which this Court considered in turn. For the reasons set forth herein, this Court will DENY Plaintiff's Motion for Summary Judgment and GRANT Defendant's Motion for Summary Judgment. Defendant's decision to exclude Plaintiff under § 1320a-7(b)(1) is affirmed.

FACTUAL BACKGROUND²

The factual record in this case is extensive, but is largely undisputed. Synthes, Inc. served as the American branch of a multinational corporation specializing in the manufacture of medical devices. (Pl. SUMF ¶1; Def. SUMF ¶1). Plaintiff, Richard Bohner, worked as Synthes's Vice President of Human Resources and Regulatory Affairs from 1997 to 2002, and then as the Vice President of Operations from January 2002 until 2004. (Def. SUMF ¶3). Norian Corporation was a Synthes subsidiary that manufactured bone cement used in surgical bone repairs. (Pl. SUMF ¶2; Def. SUMF ¶2). At the heart of Plaintiff's conviction are two Norian products manufactured for use as bone void fillers: Norian Skeletal Repair System ("SRS") and Norian XR ("XR"). (Def. SUMF ¶8). During Plaintiff's executive tenure at Synthes, the Food and Drug Administration ("FDA") cleared both SRS and its successor XR for limited surgical use, but with an explicit warning that the products were not to be mixed with any other substance. (Pl. SUMF ¶4, 5). The FDA classified both SRS and XR as "significant risk devices," indicating that

² For the sake of brevity, the Court will only cite to the movants' Statements of Undisputed Material Facts ("SUMF") where the stated fact is deemed admitted by the opposing party.

the products posed a significant risk to the health and safety of patients. (Pl. SUMF ¶3; Def. SUMF ¶9).

Despite the FDA classifications, restrictions, and warnings, Synthes and Norian promoted the off label, unauthorized use of SRS and XR to treat vertebral compression fractures. (Pl. SUMF ¶6). Synthes and Norian trained spine surgeons in the unapproved use of the Norian bone void fillers, and assisted as the surgeons went on to conduct clinical trials on human patients with the Norian bone fillers. (Def. SUMF ¶18, 20; A.R. 1376-1383). Two patients died during unauthorized clinical trials involving Norian bone fillers. (A.R. 1376-183). No autopsy was conducted for either patient to determine the cause of death, and the death of the first patient went unreported altogether. (A.R. 1376-1383).

As a result of their participation in the unauthorized use of SRS and XR, Synthes and Norian were each charged with, *inter alia*, upwards of 45 counts of introducing adulterated and misbranded medical devices into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 352(a), and 333(a). (Def. SUMF ¶12, 13). Both companies ultimately plead guilty to a variety of charges related to their promotion and unauthorized dissemination of SRS and XR. (Pl. SUMF ¶7, 8; Def. SUMF ¶24, 25).

Plaintiff and three other Synthes executives were charged with one misdemeanor count of introducing adulterated and misbranded medical devices into interstate commerce in violation of the FDCA, 21 U.S.C. §§ 331(a), 352(a), and 333(a)(1). (Def. SUMF ¶14, 15). On May 26, 2009, Plaintiff signed an agreement to plead guilty to one count of misdemeanor misbranding, a violation of 21 U.S.C. §§ 331(a). (Pl. SUMF ¶9; Def. SUMF ¶16). The crime to which Plaintiff pled guilty was a strict liability offense, requiring no evidence of intent. Plaintiff was convicted

under the “responsible corporate officer” doctrine of United States v. Park, which was introduced as a means of holding senior corporate officials responsible for their companies’ misconduct where the officials had the power and responsibility to intervene. 421 U.S. 658 (1975). (Pl. SUMF ¶10; Def. SUMF ¶16). Plaintiff’s plea agreement detailed the facts of Synthes’ illegal test marketing and promotion of SRS and XR, Plaintiff’s knowledge that the companies’ conduct violated the FDA, Plaintiff’s responsibility to prevent such violations, and Plaintiff’s complicity in “knowingly ma[king] a series of false statements to the FDA investigator.” (Def. SUMF ¶18).

On December 13, 2011 Plaintiff was sentenced to an eight-month term of imprisonment, four months of supervised release, and a maximum fine of \$100,000. (Def. SUMF ¶26). Plaintiff’s term of imprisonment represented an upward variance from the applicable Sentencing Guidelines range of zero to six months. (Def. SUMF ¶28). The sentencing judge, Judge Legrome Davis, found that the departure from the Guidelines was supported by the “unprecedented nature of the criminal conduct” of each Synthes executive charged. (Def. SUMF ¶28; A.R. 1397).

The variance is warranted because a Guidelines sentence would not adequately address the unprecedented nature of the criminal conduct of [the Synthes executives]. The scope of their scheme is without parallel, the risks created for an unsuspecting public were grave, and the scale of the deception of the Food and Drug Administration can only be characterized as extreme.

(Def. SUMF ¶28; A.R. 1397)

Judge Davis went on to conclude that this case was one of the most egregious that had come before him. (Def. SUMF ¶28; A.R. 1387-1388). Addressing the Synthes officials’ complicity in the unlawful clinical trials conducted on uninformed patients, Judge Davis had the following to say:

We have not been able to find a single case that involves such carefully constructed, meticulously implemented, and patently illegal trials....And we cannot find a case where the decision-makers ignored such clear warnings of the potentially fatal nature of the product for such an extended period. We certainly cannot find a case where the corporate actors disregarded two deaths, even failing to provide notice of the first as required by law.

(Def. SUMF ¶28; A.R. 1387-1388).

With specific reference to Plaintiff's involvement in Synthes and Norian's "scheme," Judge Davis found that "[Plaintiff] knew and was aware that the Spine Division was conducting 'test markets' that amounted to unauthorized clinical trials of SRS and XR in violation of the FDCA, and [Plaintiff] participated in conducting those trials." (Def. SUMF ¶29; A.R. 974). Judge Davis further found as fact that Plaintiff "knew at the time the clinical trials were planned and were conducted that the trials violated the FDCA." (Def. SUMF ¶29; A.R. 974).

Based on Plaintiff's conviction, the Health and Human Services' (HHS) Office of the Inspector General notified Plaintiff that he would be excluded from participation in any federal healthcare program for a period of four years, pursuant to 42 U.S.C. §1320(a)-7(b)(1). (Pl. SUMF ¶12; Def. SUMF ¶31; A.R. 753). §1320(a)-7(b)(1) reads in pertinent part:

The Secretary may exclude...any individual or entity that has been convicted...under Federal or State law...of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct (i) in connection with the delivery of a health care item or service, or with respect to any act or omission in a health care program....

PROCEDURAL HISTORY

Plaintiff requested a hearing before a HHS administrative law judge (ALJ) to challenge Defendant's exclusion decision. (Pl. SUMF ¶14). At the hearing, Plaintiff argued that Defendant, HHS Secretary Sylvia Burwell, erred in her interpretation of §1320(a)-7(b)(1) to permit Plaintiff's exclusion from program participation on the basis of his conviction for a strict liability crime. (Pl. SUMF ¶14). According to Plaintiff, §1320(a)-7(b)(1) required Defendant to apply the categorical approach to assess whether the generic elements of his offense of conviction constitute an offense "relating to fraud," as opposed to assessing whether the circumstances of Plaintiff's conduct relates to fraud. (Pl. SUMF ¶ 14). Plaintiff further argued that the D.C. Circuit case – Friedman v. Sibelius, 686 F.3d. 813 (D.C. Cir. 2012) – supporting Defendant's construction of §1320(a)-7(b)(1) to require a circumstance specific approach, was similarly erroneously decided. (Pl. SUMF ¶ 14). In a 23 page opinion, the ALJ, citing Friedman, rejected Plaintiff's challenge and affirmed the four year exclusion. (Pl. SUMF ¶ 15; Def. SUMF ¶ 32; A.R. 1-23).

Plaintiff then appealed the ALJ's decision to HHS' Departmental Appeals Board (DAB), again arguing that his conviction for a strict liability offense did not "relat[e] to fraud" as required by §1320(a)-7(b)(1). In a decision issued May 26, 2015, the DAB held that "the ALJ did not err in concluding that [Plaintiff's] exclusion was authorized under [§1320(a)-7(b)(1)] because his misdemeanor conviction was 'related to fraud.'" (Pl. SUMF ¶ 16; A.R. 38). The DAB affirmed the propriety of the circumstance specific approach to assessing eligibility for exclusion under §1320(a)-7(b)(1), and upheld Defendant's decision to exclude Plaintiff for four years. (Pl. SUMF ¶ 17; Def. SUMF ¶ 33; A.R. 30).

Having exhausted his administrative remedies, on July 24, 2015, Plaintiff timely filed this action challenging the Secretary's decision to exclude Plaintiff from participation in any federal health care program on the basis of his conviction of a strict liability offense.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(a), a court shall grant summary judgment “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine [dispute] as to any material fact and that the moving party is entitled to a summary judgment as a matter of law.” Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); FED. R. CIV. P. 56(a). “If the moving party meets its burden, the burden shifts to the nonmoving party to go beyond the pleadings and come forward with specific facts showing that there is a genuine issue for trial.” Santini v. Fuentes, 795 F.3d 410, 416 (3d Cir. 2015) (internal citations and quotation marks omitted). Therefore, in order to defeat a motion for summary judgment, the non-movant must establish that the disputes are both (1) material, meaning concerning facts that will affect the outcome of the issue under substantive law; and (2) genuine, meaning the evidence must be such that a reasonable jury could return a verdict for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.” Celotex, 477 U.S. at 322. “At the summary judgment stage of proceedings, courts do not ‘weigh the evidence or make credibility determinations,’ but, instead, leave that task to the fact-finder at a later trial if the court denies summary judgment.” Halsey v. Pfeiffer, 750 F.3d 273 (3d Cir. 2014) (quoting Petruzzi's IGA Supermarkets v. Darling-Delaware Co., 998 F.2d 1224, 1230 (3d Cir. 1993)).

Any individual or entity excluded from program participation under 42 U.S.C. §1320(a)-7 is entitled to judicial review. 42 U.S.C. §1320(a)-7(f) (incorporating by reference the standard of review delineated in 42 U.S.C. §405(g)). Pursuant to §1320(a)-7(f), the Secretary's exclusion decision shall be affirmed "if the Court finds that there was substantial evidence in support of the Secretary's determination and that the proper legal standards were applied." Kahn v. Inspector Gen. of the United States Dep't of Health & Human Servs., 848 F. Supp. 432, 436 (1994). As the parties appear to agree that there are no genuine disputes of material fact, the task before this Court is to determine whether, as a matter of law, Defendant's exclusion decision was both based upon the proper legal standard and supported by substantial evidence.

DISCUSSION

The discretionary exclusion provision at issue, 42 U.S.C. § 1320a-7(b)(1) authorizes the Secretary of HHS to exclude any individual or entity that has been convicted of a criminal offense consisting of a misdemeanor *relating to* fraud, theft, embezzlement, breach of fiduciary duty, or other financial misconduct. Defendant exercised her discretion to exclude Plaintiff from participation in any federal health care program after determining that Plaintiff's conviction for misdemeanor misbranding and adulteration "related to fraud" as required by § 1320a-7(b)(1). Defendant decided Plaintiff's crime related to fraud based on the facts surrounding Plaintiff's conviction and Plaintiff's admitted misconduct. Under Defendant's construction of § 1320a-7(b)(1), Plaintiff's exclusion was justified because Plaintiff's conduct had a common sense connection to fraud. Defendant's construction of § 1320a-7(b)(1) applies the circumstance specific approach, which considers the conduct underlying one offense to determine its relatedness to another offense.

Plaintiff argues that § 1320a-7(b)(1) predicates exclusion on a generic relationship between an individual's offense of conviction and one of the offenses enumerated in the provision. This suggested construction of § 1320a-7(b)(1) is referred to as the categorical approach. The categorical approach compares one offense to another by referencing the statutory definitions of each offense and analyzing the commonality of the offenses' statutory elements. Applying the categorical approach to § 1320a-7(b)(1), a misdemeanor would only "relate to" fraud if that offense, as statutorily defined, comprises the same elements as does fraud. Thus the crux of Plaintiff's argument is that strict liability offenses, that require no showing of culpable mental state, cannot "relate to" offenses like fraud that require scienter. Under Plaintiff's construction of § 1320a-7(b)(1), the strict liability offense of which Plaintiff was convicted cannot justify exclusion under § 1320a-7(b)(1).

Ultimately, this case turns on the first prong of the §405(g) standard –the propriety of the legal standard Defendant applied to exclude Plaintiff under § 1320a-7(b)(1). This Court cannot determine the sufficiency of the evidence to support exclusion without first determining the lens through which the evidence must be considered. As such, the pivotal question before this Court is whether, § 1320a-7(b)(1) predicates exclusion on a categorical relationship between the generic elements of Plaintiff's conviction and fraud, or instead on the relatedness of Plaintiff's misconduct to fraud. For the reasons that follow, this Court adopts the latter construction and holds that the circumstance specific approach applies to exclusion decisions under § 1320a-7(b)(1).

I. Defendant Applied the Correct Legal Standard

Whether Defendant applied the correct legal standard turns entirely on whether Defendant correctly interpreted the language of § 1320a-7(b)(1). When asked to consider an

agency's construction of a federal statute, courts ordinarily refer to the Supreme Court's decision in Chevron v. U.S.A., Inc., v. NRDC, Inc., 467 U.S. 837 (1984). In Chevron the Court delineated a two-part analysis for assessing the interpretation of federal statutes by the agencies authorized to administer them. The first step of the analysis is to determine whether, on its face, the statute at issue expresses clear congressional intent. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, 467 US at 842-843 (1984). If the statute is silent or ambiguous with respect to the specific issue, the second step of the analysis challenges the court to assess whether the agency's decision is based on a permissible construction of the statute. Id. at 843. "A court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." Id. at 844.

Plaintiff argues that the Defendant's exclusion decision is not owed Chevron deference because the challenged language of § 1320a-7(b)(1) is "commonplace criminal law terms" over which HHS has "no particular expertise." This argument is erroneously based upon a Third Circuit case in which the court afforded no deference to an agency's determination of whether a particular federal offense was an aggravated felony for the purposes of removal under the INA. Young Wong Park v. Att'y Gen. of the United States, 472 F.3d 66 (3d Cir. 2006). The court in Young Wong Park found that the defendant had "no particular expertise in defining a term under federal law," and that "legal issues that turn on a pure question of law not implicating the agency's expertise do not raise the same concerns under [Chevron]." Id. at 71. The Young Wong Park case is distinguishable from the case at bar. "Relating to" is not a legal term of art for which the federal government is uniquely positioned to provide interpretive guidance. In contrast, HHS – having been charged with administering the statute at issue – is much better equipped to assess

the congressional intent underlying the exclusion provision. This Court rejects Plaintiff's claim that Young Wong Park is applicable and finds that Chevron is the appropriate standard by which to assess the Defendant's interpretation of § 1320a-7(b)(1).

According to the Court in Chevron, the clarity of Congress's intent is to be determined by "employing traditional tools of statutory construction." Chevron, 467 U.S. at 843 n. 9. Applying said tools and for the reasons that follow, this Court finds that Congress's intent is clear on the face of § 1320a-7(b)(1). The language of the exclusionary provision and the legislative intent of the Act authorizes – if not requires – the Secretary to consider the factual circumstances surrounding an individual's conviction when deciding whether exclusion is appropriate under § 1320a-7(b)(1). Accordingly, we do not need to reach the question of whether the Defendant's interpretation of the exclusion provision is reasonable. The Defendant acted in accordance with the apparent intent of Congress so Defendant's interpretation of the statute is inherently permissible. Defendant applied the proper legal standard when Defendant considered the facts underlying Plaintiff's conviction and determined Plaintiff was eligible for exclusion under § 1320a-7(b)(1).

A. The plain language of § 1320a-7(b)(1) and surrounding text support the application of the circumstance specific approach.

1. The ordinary meaning of "relating to" compels a circumstance specific approach to exclusion decisions.

"The text of a statute or rule is the primary, essential source of its meaning." UNIF. STATUTE & RULE CONSTR. ACT §19 (1995). A fundamental canon of statutory construction is that, in the absence of congressional intent to the contrary, statutory terms are given their "ordinary, contemporary, common meaning." Perrin v. United States, 444 U.S. 37, 42 (1971) (citing Burns v. Alcala, 420 U.S. 575, 580-81 (1975)). The ordinary and plain definition of

“relating to” is “to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.” Morales v. Trans World Airline, 504 U.S. 374, 383 (1992). Under this construction, the preposition “relating to” encompasses anything that has a connection to or is associated with the specified object. Thus, by its plain terms, § 1320a-7(b)(1) classifies any offense having a connection to or an association with “fraud,” “theft,” “embezzlement,” “breach of fiduciary responsibility,” or “financial misconduct” as an excludable offense.

Despite the breadth of its plain meaning, Plaintiff asks this Court to construe “relating to” to only encompass the offenses statutorily modeled after the generic crimes of “fraud”, “theft”, “embezzlement”, and “breach of fiduciary responsibility.” Plaintiff argues that the plain language of § 1320a-7(b)(1) focuses on the relationship between the offense of conviction and the elements of the crimes enumerated in the provision. (Pl. Mot. Sum. J., 8). The categorical approach for which Plaintiff advocates requires the court to abandon what is commonly understood of the phrase “relating to” and employ a reading that is “cramped” and unsupported by anything “in the statute or legislative history.” Friedman v. Sebelius, 755 F. Supp. 2d 98, 107 (2010) (considering an almost identical question of whether § 1320a-7(b)(1) requires a categorical approach to exclusion decisions) (rev’d and remanded on other grounds by Friedman v. Sebelius 686 F.3d 813 (D.C. Cir. 2012)).

As noted by the D.C. district court in Friedman, Plaintiff’s suggested construction of § 1320a-7(b)(1) would all but read “relating to” out of the statute altogether. Friedman, 755 F. Supp. 2d at 108. The Rule against Surplusage, instructs the court to interpret a statute such that each word has meaning; nothing is redundant, inoperative, void, or superfluous. Corley v. United States, 556 U.S. 303, 314 (2009). Under Plaintiff’s narrow reading of § 1320a-7(b)(1) the words

“relating to” are completely unnecessary, as § 1320a-7(b)(1) effectively only authorizes exclusion on the basis of actual convictions for “fraud”, “theft”, “embezzlement” or “breach of fiduciary responsibility” offenses. If Congress intended for § 1320a-7(b)(1) to be interpreted as Plaintiff suggests, it would have been simple enough to write the statute as allowing for exclusion only where an “individual or entity [is] convicted...under Federal or State law...of a misdemeanor offense of fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.”

That Congress instead chose to include “relating to” in the text of § 1320a-7(b)(1) indicates an intention to give meaning and function to the phrase. As this Court finds no evidence to suggest that Congress intended to ascribe an unconventional meaning to “relating to,” this Court applies its ordinary meaning. The ordinary meaning of “relating to” as it appears in § 1320a-7(b)(1) compels the application of the circumstance specific approach to HHS decisions to exclude convicted individuals from federal health care program participation.

2. The “relating to” language appears in other provisions of the Act where application of the categorical approach would be indefensible.

The “relating to” language appears in nearly every provision of § 1320a-7. The phrase “relating to” is used throughout § 1320a-7 under circumstances where the only logical construction of the phrase requires assessment of factual connectedness. Consider a provision immediately following § 1320a-7(b)(1). § 1320a-7(b)(2) reads: “The Secretary may exclude...any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit *related to...*(2) the use of funds received, directly or indirectly, from any Federal health care program....” (emphasis added). “Investigation or audit related to the use of funds received” does not denote a

generic class of investigations or audits. The provision inherently requires the Secretary to consider the facts surrounding an individual's conviction to see if the investigation or audit in question was associated with or connected to funds received from a federal healthcare program.

The Presumption of Consistent Usage is a linguistic canon that presumes that when the legislature uses the same words or phrases in different parts of the same act, the legislature intended those words or phrases to have the same meaning. Department of Revenue v. ACF Indus., 510 U.S. 332, 342 (1994) (internal citations omitted). This canon can be rebutted with evidence that a different meaning was intended, Atlantic Cleaners & Dryers, Inc. v. United States, 286 U.S. 427, 433 (1932), but in the absence of such evidence, courts are instructed to interpret a statute as being internally consistent. Gustafson v. Alloyd Co., Inc., 513 U.S. 561, 567-569 (1995). This Court finds it difficult to believe the Congress employed “relating to” in one provision of a statute to indicate a generic categorical connection, and employed identical language in the very next provision to denote factual connectedness. The “relating to” language of § 1320a-7(b)(2) cannot reasonably be read to apply categorically, so employing the Presumption of Consistent Usage, the only reasonable interpretation is that the “relating to” language refers to factual connections wherever it appears in the statute.

3. The “other financial misconduct” language is further indicia of Congress’s intent to require the circumstance specific approach.

The catchall phrase of § 1320a-7(b)(1), which allows Defendant to exclude parties convicted of misdemeanor offenses related to “financial misconduct,” all but fatally undercuts Plaintiff’s position. Under Plaintiff’s cabined reading of the HHS exclusionary provision, for an individual to be excluded on the basis of a conviction for a misdemeanor offense “related to” financial misconduct, the individual’s offense of conviction must share the same generic

elements as a crime of financial misconduct. The flaw in that reasoning, however, is that there is no particularized crime of “financial misconduct” to which we can compare the elements of an offense of conviction. As noted by the D.C. Court of Appeals in Friedman, “[t]he residual clause ‘other financial misconduct’ expressly refers to a type of ‘conduct’ not a genus of criminal offense.” 686 F.3d at 821. “The relationship of a ‘misdemeanor’ to ‘other financial misconduct’ must therefore be a factual one.” Id.

It is Plaintiff’s contention that a court could reasonably apply a categorical approach to misdemeanor offenses relating to “other financial misconduct.” According to Plaintiff, “a conviction under an anti-money laundering law that prohibits ‘structuring any transaction with....financial institutions’ for the purpose of evading financial institution reporting contracts” categorically relates to financial misconduct. (Pl. Reply, 7). Not only is this example contrary to Plaintiff’s expressed position up to this point, it exemplifies the superiority of the circumstance specific approach over the categorical approach to § 1320a-7(b)(1).

Up to this point, Plaintiff argued that an offense can only “relate to fraud” under § 1320a-7(b)(1) where the offense is “*by its nature*” a fraud offense, complete with the requisite elements of fraud – like scienter. (Pl. Mot. Sum. J., 8; Pl. Br. Opp., 1). It follows, then, that an offense can only “relate to financial misconduct” where the offense of conviction is, by its nature, a financial misconduct offense that has all the requisite elements of financial misconduct. The parties have yet to identify, and this Court has yet to uncover, a generic criminal offense of financial misconduct to which HHS could categorically compare an individual’s offense of conviction for exclusion decisions under § 1320a-7(b)(1). If, as a logistical matter, an individual could never be excluded for conviction of an offense that relates to financial misconduct under a categorical theory of “related to,” Plaintiff’s proposed approach is inoperable. It would render the residual

clause of § 1320a-7(b)(1) void and unworkable. This Court is required to read § 1320a-7(b)(1) in a way that gives meaning to every word, so we must reject a categorical application of “related to,” here.

In contrast, an application of the circumstance specific approach considers what the criminal act entails – as Plaintiff appears to in his anti-money laundering example – and whether the individual’s conduct is factually related to financial misconduct. Based on Plaintiff’s description of the money laundering, the offense does not specifically have “financial misconduct” as an element. Rather, conduct underlying the described violation would seem to have a common sense connection to the concept of financial misconduct. Even with Plaintiff’s own proffered example, the circumstance specific approach appears to be the only viable means of evaluation.

B. The Legislative Evolution § 1320a-7(b)(1) Demonstrates Congress’s Intent to Afford Defendant Broad Discretion over Exclusion Decisions

42 U.S.C § 1320a-7 was amended in 1987 to include both the provision at issue, and all other provisions that authorize exclusion of persons “convicted of offenses relating to their financial integrity” or professional competence. S. Rep. No. 100-109 at *7 (1987). The express purpose of the 1987 amendment was to “improve the ability of [HHS] to protect [federal health care programs] from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from inappropriate or inadequate care.” S. Rep. No. 100-109 at *1-2 (1987). Before the 1987 amendment, HHS could not exclude individuals or entities convicted of criminal offenses unrelated to government health care programs. § 1320a-7(b)(1) was added to “[broaden] the grounds for the discretionary exclusion of health care providers.” S. Rep. No. 100-109 at *2 (1987). In light of the express legislative intent to protect federal programs and

their beneficiaries from bad actors, this Court finds it unlikely that Congress would restrict HHS's power to exclude in the way Plaintiff suggests.

Plaintiff encouraged the unapproved use of dangerous medical devices and sanctioned unauthorized clinical trials on human patients. Plaintiff's conduct is the exact kind of abuse against which § 1320a-7(b)(1) was designed to protect. This Court finds no indication in 1320a-7(b)(1)'s statutory language or legislative history that the requisite for exclusion is, essentially, a conviction of one of the enumerated offenses. To the contrary, the unambiguous text and express statutory purpose both indicate a broad authority to base program exclusions on abusive or fraudulent misconduct.

C. § 1320a-7(b)(1) is distinguishable from the INA provision applying the categorical approach.

Much of Plaintiff's argument in favor of the categorical approach rests on the Supreme Court's holdings in a line of Immigration and Nationality Act ("INA") deportation cases, the most recent of which is Mellouli v. Lynch, 135 S. Ct. 1980 (2015). In Mellouli, the Court considered whether a potential deportee's state conviction for possessing drug paraphernalia triggered removal under 8 U.S.C. § 1227(a)(2)(B)(i). Id. § 1227(a)(2)(B)(i) authorized deportation of a noncitizen "convicted of a violation of...any law or regulation of a State, the United States, or a foreign country relating to a controlled substance (as defined in section 802 of Title 21)." Id. at 1981-1982. In applying the categorical approach the Court considered the statutory definition of the potential deportee's offense of conviction and held that it did not "fall within a category of offenses" that would trigger removal under § 1227(a)(2)(B)(i). Id. at 1986. In interpreting the removal provision, the Court held that Congress intentionally predicated deportation under § 1227(a)(2)(B)(i) on "convictions not conduct," signaling that the "statutory

definition of the offense of conviction, not the particulars of [a] [non-citizen's] behavior" was determinative. Id. Because both the INA removal provision and § 1320a-7(b)(1) share the "relating to" language, Plaintiff argues that this Court should follow the same reasoning of the Mellouli Court and find that Plaintiff's "actual conduct is irrelevant" to his eligibility for exclusion.

Plaintiff argues that § 1227(a)(2)(B)(i) is "nearly identical" to § 1320(a)-7(b)(1). This Court could not disagree more. While both provisions predicate a collateral consequence on conviction of uniquely qualified crimes, the statutes' legislative histories, the referents of "relating to," and the nature of the related proceedings are all meaningfully different. Mellouli and its INA predecessors are inapposite, and this Court is, thus, not bound by their holdings.

The plain language of § 1227(a)(2)(B)(i) reflects Congress's intention to limit the cases in which a non-citizen could be deported for a drug related state conviction. In § 1227(a)(2)(B)(i), "relating to" links "law or regulation" to federally "controlled substances." An assessment of a particular law or regulation necessitates an assessment of the elements it comprises. The majority in Mellouli confirmed as much. "To trigger removal under § 1227(a)(2)(B)(i), the Government must connect an element of the alien's conviction to a drug defined in [§ 802]." Mellouli, 135 S. Ct. at 1991. In contrast, in § 1320(a)-7(b)(1) "relating to" links "misdemeanor" to a host of enumerated offenses. Misdemeanors are a special classification of crime, and a crime is defined as an *act* that the law makes punishable. BLACK'S LAW DICTIONARY (9th ed. 2009). Thus, in § 1320(a)-7(b)(1) the focus is on characterizing wrongful acts, while § 1227(a)(2)(B)(i) focuses on comparing the laws of two independent jurisdictions.

Moreover, the unique circumstances surrounding INA proceedings require a narrow interpretation of the statute. “Rooted in Congress’[s] specification of conviction, not conduct, as the trigger for immigration consequences, the categorical approach is suited to the realities of the system.” Mellouli, 135 S. Ct. at 1986. There can be years between an individual’s conviction and the resolution of deportation proceedings, Id. at 1987, and noncitizens are not guaranteed legal representation during the removal process. Moncrieffe v. Holder, 133 S. Ct. 1678, 1690 (2013). If each noncitizen was required to re-litigate the facts of his case pro se and immigration judges were required to consider whether those particularized facts merit removal, it would exacerbate an already burdened system. The INA removal provision requires a comparison of state and federal laws in a high-stake setting where the time that can be allotted to each individual case is limited. The most efficient means of making quick and standardized comparisons of the laws is to apply the categorical approach, which focuses on “what a conviction *necessarily* established.” Mellouli, 135 S. Ct. at 1987.

These are not the circumstances from which exclusion decisions under § 1320(a)-7(b)(1) arise. Exclusion from federal health care program participation is not nearly as extreme a course of action as deportation. Defendant is presumably not burdened in the way that immigration judges are, and § 1320(a)-7(b)(1) promotes the exercise of discretion in a way that is expressly discouraged in immigration proceedings. Moncrieffe, 133 S. Ct. at 1690 (noting that the categorical approach avoids the “potential unfairness” that could result from immigration judges conducting *post hoc* investigations into the facts of predicate offenses). Although both § 1227(a)(2)(B)(i) and § 1320a-7(b)(1) employ “relating to,” the phrase operates in two radically different circumstances and rightfully yields two different results.

D. § 1320a-7(b)(1) is distinguishable from the ACCA provision applying the categorical approach.

In a Notice of Supplemental Authority, Plaintiff alerted this Court to a Supreme Court decision applying the categorical approach to a provision in the Armed Career Criminal Act (“ACCA”). For many of the same reasons detailed in the foregoing section distinguishing § 1320a-7(b)(1) from a similarly worded INA provision, this Court finds Plaintiff’s comparison of § 1320a-7(b)(1) to the ACCA inapposite. Specifically, this Court finds that the wording of the ACCA provision and the general nature of ACCA proceedings compel the use of the categorical approach in a way that the statutory language of § 1320a-7(b)(1) and the nature of related exclusion proceedings do not.

In Mathis, the Court considered an ACCA provision that imposes a fifteen year mandatory minimum sentence on federal defendants who have three prior convictions for a “violent felony.” Mathis v. United States, 136 S. Ct. 2243, 2248 (2016); 18 U.S.C. § 924(e). Notably, § 924(e) does not contain the “relating to” language at issue in § 1320a-7(b)(1), and instead specifically predicates the imposition of an enhanced sentence on “three prior convictions by any court....for a violent felony or a serious drug offense....” Such language constitutes an express statutory directive to apply the categorical approach and is materially distinct from the language employed in § 1320a-7(b)(1). The nature of criminal sentencing proceedings involving the ACCA are also wholly distinct from the administrative exclusion proceedings involving § 1320a-7(b)(1). The application of the circumstance specific approach to § 924(e) would raise serious Sixth Amendment concerns not at issue in HHS exclusion proceedings. Mathis 136 S. Ct. at 2252. Because, under the Sixth Amendment, “only a jury, and not a judge, may find facts that increase a maximum penalty,” a sentencing judge applying § 924(e) “can do no more...than determine what crime, with what elements, the defendant was convicted of.” Id.

Thus, Plaintiff's attempt to liken the ACCA to § 1320a-7(b)(1) is untenable because both the text of § 924(e) and the nature of the related criminal proceedings require the application of the categorical approach. In contrast and as explained above, the text of § 1320a-7(b)(1), its express purpose, and the nature of related HHS proceedings all support the use of the circumstance specific approach to determining eligibility for exclusion under § 1320a-7(b)(1).

E. The circumstance specific approach does not implicate Due Process Concerns.

Finally, Plaintiff encourages this Court to reject the circumstance specific approach on the grounds that its application violates the Due Process Clause of the Fifth Amendment. Plaintiff argues that the circumstance specific approach "provides no guidance regarding what offenses the Secretary might determine... '[relate] to' fraud," and results in arbitrary and discriminatory enforcement of § 1320a-7(b)(1). (Pl. Mot. Sum. J., 16). Plaintiff's concerns are without merit. § 1320a-7(b) was intentionally drafted to grant the HHS discretionary authority to exclude individuals eligible by virtue of their criminal acts. That the decisions are discretionary inherently means that individuals cannot say with certainty which misconduct will yield exclusion and which will not. But the standard provided by this Court, the holdings of other federal courts on this issue³, and the countless HHS administrative opinions upholding the circumstance specific approach is of significant predictive value. Where an individual is convicted of an offense under circumstances that share a common sense connection to fraud, theft, embezzlement, breach of fiduciary responsibility, or financial misconduct, that individual is eligible for exclusion under § 1320a-7(b)(1). Notably, Plaintiff was warned at his plea

³ Friedman v. Sebelius, 755 F. Supp. 2d 98, 107 (2010) (considering an almost identical question of whether § 1320a-7(b)(1) requires a categorical approach to exclusion decisions) (rev'd and remanded on other grounds by Friedman v. Sebelius 686 F.3d 813 (D.C. Cir. 2012)); Patel v. Thompson, 319 F. 3d 1317 (11th Cir. 2003)("We thus see nothing in section 1128(a)(2) that requires that the necessary element of the criminal offense must mirror the elements of the exclusion authority....")(aff'g Neandra M. Patel, M.D DAB No. 1736 at 7(2000)).

colloquy that exclusion under § 1320a-7(b)(1) was a potential collateral consequence of his plea. Thus even the record in this case demonstrates the clarity of the circumstance specific approach and its ability to notice individuals of the potential consequences of their misdeeds.

While this Court does not discount the serious consequences that could result from exclusion, we think it important to stress that § 1320a-7(b)(1) is not intended to punish or deprive individuals of employment. The statute is intended to protect federal health care programs and afford the government a say in the kind of people with whom it contracts. The Constitution does not guarantee Plaintiff a right to contract with a particular government program after having defrauded that very same program.

II. **There is Substantial Evidence on the Record to Support Defendant's Decision**

Applying the circumstance specific approach, it is abundantly clear that there is substantial evidence in the record to justify Defendant's decision to exclude Plaintiff from program participation under § 1320a-7(b)(1). As demonstrated by Plaintiff's plea and Judge Davis's factual findings, Plaintiff knowingly encouraged the off label use of SRS and XR without FDA approval, participated in illegal clinical trials which resulted in the death of two patients, and made false statements to an FDA investigator. As so aptly stated by the ALJ in Plaintiff's first administrative hearing, "from these admitted facts I can reasonably infer – indeed, I find no other inference reasonable – that...these facts...establish [Plaintiff's] offense is related to fraud." A.R. 7, 9.

CONCLUSION

In New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., the Supreme Court cautioned that "relating to," when "extended to the furthest stretch of its indeterminacy...stops nowhere." 514 U.S. 645, 655 (1995). This Court takes heed to that

warning. Just as this Court recognizes that context may “tug in favor of a narrower meaning” of “relating to,” Yates v. United States, 135 S. Ct. 1074, 1083 (2015), so too does this Court acknowledge that context may afford the phrase its full breadth.

This Court finds that the plain language of § 1320a-7(b)(1), its statutory history, and legislative purpose all support Defendant’s application of the circumstances specific approach. The use of “relating to” in the context of immigration proceedings is inapposite because of the marked differences in the drafting and nature of the respective statutes. Congress granted HHS – and Defendant by extension – broad authority to protect federal health care programs and their beneficiaries. The circumstance specific approach is the best means of fulfilling that objective. Under the circumstance specific approach, the record is rife with evidence of Plaintiff’s egregious and fraudulent conduct. Thus, Defendant’s decision to exclude Plaintiff from program participation under § 1320a-7(b)(1) was based on both the correct legal standard and substantial evidence of Plaintiff’s excludable conduct.

For these and the foregoing reasons, this Court hereby denies Plaintiff’s Motion for Summary Judgment, grants Defendant’s Motion for Summary Judgment, and affirms the Secretary’s decision to exclude Plaintiff under 42 U.S.C. § 1320a-7(b)(1).

BY THE COURT:

C. Darnell Jones, II

C. Darnell Jones, II J.